

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,)	
)	
Plaintiff,)	C.A. No. 20-125 (LPS)
)	(CONSOLIDATED)
v.)	
)	JURY TRIAL DEMANDED
ARCHERDX, INC., ARCHERDX, LLC and)	
INVITAE CORP.,)	REDACTED –
)	PUBLIC VERSION
Defendants.)	

**OPENING BRIEF IN SUPPORT OF NATERA, INC.'S MOTIONS FOR
PARTIAL SUMMARY JUDGMENT AND TO PRECLUDE CERTAIN EXPERT
TESTIMONY**

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I. SUMMARY OF ARGUMENT

Defendants ArcherDX, Inc., ArcherDX LLC and Invitae Corp. (collectively “Defendants”) have adopted the everything but the kitchen sink approach in this litigation, asserting defenses of questionable legal bases and infirm factual support. To streamline the case, Plaintiff Natera, Inc. (“Natera”) seeks summary judgment on (1) the equitable defenses of prosecution laches, unclean hands, and inequitable conduct and the related invalidity defense of improper inventorship, (2) an invalidity defense – that the asserted claims supposedly do not state what the applicants regarded as their invention, and (3) an indefiniteness defense that was inadequate at the *Markman* stage and continues to remain inadequate now with no new relevant evidence.

Defendants’ equitable defenses fall far short of their heightened burden of proof. Defendants cannot demonstrate either of the two elements of prosecution laches: a delay in prosecution of Natera’s cfDNA Patents¹, let alone an unreasonable and inexcusable delay, or intervening rights. The cfDNA Patent applications issued within a year of filing and Natera diligently prosecuted 13 applications, 6 of which issued as patents, during the 7-8-year period between the filings of the priority application and the cfDNA Patent applications. Courts have granted summary judgment of no prosecution laches under similar circumstances.

Defendants also cannot demonstrate unclean hands, which rests upon essentially the same support as for prosecution laches. Their additional perfunctory allegation that a former Natera executive had access to ArcherDX’s confidential information is of no moment: Defendants admit that they have no evidence that *Natera* had access to Defendants’ confidential information.

¹ cfDNA Patents corresponds to 4 of the Asserted Patents: U.S. Patent Nos. 10,538,814 (the “814 Patent”), Ex. 1, 10,557,172 (the “172 Patent”), Ex. 2, 10,590,482 (the “482 Patent”), Ex. 3, and 10,731,220 (the “220 Patent”), Ex. 4. All exhibits are to the Declaration of Bhanu K. Sadasivan filed herewith.

Defendants' inequitable conduct defense, based on allegations of improper correction of inventorship and non-disclosure of litigation documents, fares no better. Defendants cannot clearly demonstrate that change in inventorship or non-disclosure to the PTO of pleadings and briefs from this and other litigations is but-for material such that the patent would not have issued. Defendants also cannot show that an intent to deceive the PTO is the only inference that can be reached from correction of inventorship or non-disclosure of litigation documents.

Likewise, Defendants' attempt to invalidate the cfDNA Patents based on alleged improper inventorship is legally void. 35 U.S.C. § 256 makes clear that a patent may not be invalidated for improper inventorship regardless of whether it was a mistake or the product of deception. The remedy is to correct inventorship and any assertion of intentional conduct is handled by the separate defense of inequitable conduct – which founders for the reasons discussed above. Defendants further fail to identify any corroborating evidence of conception necessary for nonjoinder or misjoinder, which renders their defense legally infirm.

Natera further brings two motions under *Daubert*. The first seeks to preclude testimony of Defendants' patent law expert on prosecution laches because the expert does not bring any specialized knowledge on PTO practice and procedure to bear on his testimony, and improperly speculates about Natera's state of mind. The law in this District is settled that such legal experts would be unhelpful to a trier of fact. Natera further seeks to preclude Defendants' expert's opinion on improper inventorship because he relies solely on *uncorroborated* select inventor testimony excerpts and did not undertake the requisite analysis. As a matter of law, uncorroborated evidence is legally insufficient to prove inventorship, and in any event, the testimony does nothing more than seek to usurp the role of the jury.

Natera respectfully requests that the Court grant summary judgment on these strained defenses and preclude expert testimony related to the defenses.

II. NATURE AND STAGE OF THE PROCEEDINGS

Defendants have infringed and are continuing to infringe Natera's patents to compete with Natera in the oncology market. Indeed, every ArcherDX product uses Natera's patented method. On January 27, 2020, Natera filed suit against Defendants to stop their ongoing infringement. D.I. 1. Natera is currently asserting five patents against Defendants: U.S. Patent Nos. 10,538,814 (the "'814 Patent"), Ex. 1; 10,557,172 (the "'172 Patent"), Ex. 2, 10,590,482 (the "'482 Patent"), Ex. 3, 10,731,220 (the "'220 Patent"), Ex. 4 and 10,597,708 (the "'708 Patent"), Ex. 5. D.I. 391.

Immediately after Natera filed the Complaint, Defendants initiated their attacks on the validity of the patents. Defendants moved for judgment on the pleadings that the '814 Patent, '172 Patent, and '482 Patents were unpatentable under Section 101. D.I. 23. The Court denied their motion finding that the patents are directed to patentable subject matter. D.I. 63. Defendants then attacked the asserted claims of the '814, '220 and '708 Patents as indefinite. D.I. 177. The Court again rejected their arguments finding that Defendants had failed to provide clear and convincing evidence of indefiniteness at that stage. D.I. 243. Natera requested and was granted correction of inventorship of the '814, '172, '482 and '220 Patents (the "cfDNA Patents") by the PTO. Ex. 6, NAT-AR-00703199; Ex. 7, NAT-AR-00703166; Ex. 8, NAT-AR-00703099; Ex. 9, NAT-AR-00703132. Defendants have since added a defense of inequitable conduct based on improper inventorship. D.I. 393.

Both fact and expert discovery in this case have closed. Defendants are unable to point to any evidence sufficient for a reasonable jury to find for Defendants on the defenses subject to this motion.

III. STATEMENT OF UNDISPUTED MATERIAL FACTS

The undisputed material facts relevant for the requested grounds for summary judgment and preclusion of expert testimony are set forth here. Additional undisputed material facts are included in the arguments below.

A. NATERA’S PROSECUTION OF THE cfDNA PATENTS

Natera’s prosecution of the four applications that issued as the cfDNA Patents took less than one year:

Patent No.	Application Filing Date	Issue Date of Patent	Total Prosecution Time
10,538,814	4/30/2019	1/21/2020	266 days (< 9 months)
10,557,172	4/30/2019	2/11/2020	287 days (< 10 months)
10,590,482	4/30/2019	3/17/2020	322 days (< 11 months)
10,731,220	1/15/2020	8/4/2020	202 days (< 7 months)

Ex. 1, NAT-AR-00000001-198 at NAT-AR-00000001-2 (the ’814 Patent); Ex. 2, NAT-AR-00000199-395 at NAT-AR-00000199-200 (the ’172 Patent); Ex. 3, NAT-AR-00000396-447 at NAT-AR-00000396-397 (the ’482 Patent); Ex. 4, NAT-AR-00000872-1070 at NAT-AR-00000872-873 (the ’220 Patent); *see also* Ex. 10, Kelley Tr., 69:10-23 (“The final applications that issued as the cfDNA patents issued, all four of them, very quickly. We – less than a year when they were ultimately filed.”).

The cfDNA Patents claim priority to U.S. Application No. 13/300,235, which was filed on November 18, 2011. It is undisputed that the priority application was published (and thus, in the public domain) on October 25, 2012. *Id.*; *see also* Ex. 10, Kelley Tr., 60:21-61:10 (“I would agree that the subject matter that is disclosed in this publication is in the public domain as of its publication date”). From the filing of the priority application in 2011 to the issuance of the cfDNA

Patents, Natera diligently prosecuted 13 additional applications in the same family, 6 of which issued as patents claiming various other aspects of the inventions disclosed in these related applications. Exs. 1-4 (“Related U.S. Application Data” sections). Defendants have presented no evidence that Natera deliberately made repetitive requests for the maximum extensions of time to respond to office actions, repeatedly failed to file applications without missing parts (or other improper formalities) to extend prosecution, or deliberately refiled continuation applications for claims that had already been adjudicated on the merits to unreasonably delay prosecution in order to delay issuance of its patents. Ex. 10, Kelley Tr., 67:3-68:7.

It’s undisputed that Natera had no access to Defendants’ confidential information when prosecuting the Asserted Patents and related applications. Defendants’ 30(b)(6) witness who testified on factual information regarding Defendants’ unclean hands defense admitted that Defendants were unaware that Natera had taken any confidential information of Defendants.

Q All right. And you’re not aware of any information that came to the defendants’ attention that, in fact, Natera had taken any confidential information, correct?

THE WITNESS: Yes. We don’t know what may or may not have been transferred, and I don’t believe that -- that anything was found.

Ex. 16, 11/22/2021 Stahl Tr., 19:20-20:3.

B. DEFENDANTS’ KNOWLEDGE OF NATERA’S INVENTIONS

Defendants were aware of Natera’s application No. 13/335,043 (“the ’043 application”), a related application in the same family and having similar disclosure as the cfDNA Patents. The ’043 application published as Ryan *et al.*, U.S. Pub. No. 2012/0122701 in May 2012. Ex. 13, Ryan Publication. The Ryan publication was cited as prior art reference by the PTO examiner on December 16, 2014 during the prosecution of U.S. Patent No. 10,017,810, Iafrate *et al.* (who is a co-founder of ArcherDX). Ex. 14, NAT-AR-00708685 at NAT-AR-00708812-NAT-AR-00708820. Defendants cited the Ryan publication as a prior art reference during the prosecution

of ArcherDX's patent U.S. 10,450,597. Ex. 15, NAT-AR-00708365 at NAT-AR-00708516-NAT-AR-00708527.

C. CORRECTION OF INVENTORSHIP

Natera sought to correct inventorship in the issued Asserted cfDNA Patents in compliance with all of the PTO's requirements as set forth in 37 C.F.R. § 1.324.

With respect to the '814, '172, and '220 Patents, each of the named inventors, added inventors, and assignee Natera, submitted a signed statement under 37 C.F.R. § 1.324 agreeing to the change of inventorship of these patents "in adding Johan Baner, Milena Banjevic, Allison Ryan and Zachary Demko and removing Joshua Babiarz, Tudor Pompilin Constantin, Lane A. Eubank, Huseyin Eser Kirkizlar and Onur Sakarya as named Inventors of this patent." Ex. 17, NAT-AR-00703067-703099; Ex. 18, NAT-AR-00703100-703131; Ex. 20, NAT-AR-00703167-703198.

With respect to the '482 Patent, each of the named inventors, added inventor Bernhard Zimmermann, and assignee Natera, submitted a signed statement under 37 C.F.R. § 1.324 agreeing to the change of inventorship of the '482 Patent "in adding Bernhard Zimmermann as a named Inventors of this patent." Ex. 19, NAT-AR-00703140-703164.

The PTO issued certificates of correction. Ex. 6, NAT-AR-00703199; Ex. 7, NAT-AR-00703166; Ex. 8, NAT-AR-00703099; Ex. 9, NAT-AR-00703132.

IV. ARGUMENT

A. DEFENDANTS' PROSECUTION LACHES DEFENSE SHOULD BE DISMISSED

Defendants assert that the cfDNA Patents are unenforceable by reason of prosecution laches. Defendants, however, have failed to produce any evidence demonstrating any delay in prosecution or resulting prejudice. "[P]rosecution laches requires proving two elements: (a) that the patentee's delay in prosecution was unreasonable and inexcusable under the totality of circumstances, and (b) that the accused infringer suffered prejudice attributable to the delay."

Hyatt v. Hirshfeld, 998 F.3d 1347, 1362 (Fed. Cir. 2021). Defendants have failed to meet their heavy burden of establishing this equitable defense, applicable only in rare and extreme cases involving abusive delays of the patenting process. *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., L.P.*, 422 F.3d 1378, 1384-85 (Fed. Cir. 2005) (“Symbol III”); *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., L.P.*, 277 F.3d 1361, 1363-64 (Fed. Cir. 2002) (“Symbol I”).

1. Natera Did Not Delay Prosecuting The cfDNA Patents

Defendants have failed to show any delay in prosecuting the cfDNA Patents, let alone any unreasonable and inexcusable delay under the totality of circumstances. In fact, Natera’s prosecution of these patents was fully consistent with its diligent patent prosecution practices. The prosecution of the four applications that issued as the cfDNA Patents each took less than one year:

Patent No.	Application Filing Date	Issue Date of Patent
10,538,814	4/30/2019	1/21/2020
10,557,172	4/30/2019	2/11/2020
10,590,482	4/30/2019	3/17/2020
10,731,220	1/15/2020	8/4/2020

Notably, Natera also diligently prosecuted the entire family of related patents that arose from the same priority filings. And between the filing of these priority applications in 2011 and issuance of the cfDNA Patents, Natera prosecuted 13 additional applications in the same family, 6 of which issued as patents claiming various other aspects of the inventions disclosed in these related applications. *See supra*, Section III.A.

None of these facts are disputed. Defendants do not contend that Natera delayed in prosecuting the four applications that issued as the cfDNA Patents. Ex. 23, Stoll Report, ¶ 69; Ex. 10, Kelley Tr., 69:10-23 (“The final applications that issued as the cfDNA patents issued, all four of them, very quickly. We – less than a year when they were ultimately filed.”) Instead, Defendants’ principal complaint is with lawful continuation practice itself, arguing that Natera unreasonably delayed in submitting the claims at issue until 2019, when it allegedly could have submitted them in 2012. Ex. 24, Kelley Opening Report, ¶ 91 (“Natera’s patent prosecution conduct reflects a pattern of introducing new claims to previously un-claimed inventions for examination many years following the filing of earlier applications to which the later-filed applications claim priority.”); Ex. 10, Kelley Tr., 63:3-64:5 (“I saw a delay in the prosecution of the claims that ultimately issued in the asserted cfDNA patents...I saw other applicant-caused delays within the prosecution, but none that I have identified as – as a particular unreasonable delay.”). Defendants’ argument is legally flawed and factually unsupported.

Other than the 20-year patent term limit,² there is no requirement that a patentee *claim* each and every invention disclosed in a priority application within any particular time period. The Federal Circuit and its predecessor court have repeatedly held that there is no significance to whether *claims* are presented “late,” *i.e.*, in a continuation or divisional application, so long as they are supported by the original specification. *Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981)

² Under GATT, adopted by the United States as of June 8, 1995, the term of a utility patent is generally 20 years from the filing date of the earliest U.S. or international utility application to which priority is claimed. All the cfDNA Patents were filed after June 1995 (post-GATT). *Cordance*, 631 F. Supp. 2d at 492 (“the court notes that Cordance’s patents were all filed after June 1995, and, therefore, was not extending its patents’ term by delaying to file the claims of the ’710 patent.”). Defendants and the public had full notice of Natera’s inventions when the ’235 priority application published in 2012, which was not kept confidential by the PTO (35 U.S.C. § 122(b)), as would be the case in a pre-GATT filing. There is no prejudice to Defendants from patent term extension or lack of public availability of Natera inventions.

(rejecting idea that late presentation of claims, coupled with intervening rights, invalidates claims, and holding that “late claiming” doctrine relates only to whether the patentee “had adequate support in his disclosure, as of its filing date, for the later submitted claims:); *Correge v. Murphy*, 705 F.2d 1326, 1329 n.4 (Fed. Cir. 1983) (holding that “[i]n light of the sufficiency of the disclosure, Correge cannot raise any so-called ‘late claiming’ issue”); *Symbol III*, 422 F.3d at 1385 (“Commonly, and justifiably, one might refile an application to add subject matter in order to attempt to support broader claims as the development of an invention progresses...One may also refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive.”)

Defendants nonetheless argue that Natera delayed in presenting the asserted claims for prosecution for approximately 7.6 to 8.3 years. Ex. 24, Kelly Opening Report, ¶ 93. Defendants are wrong. “Duration of prosecution however, does not provide a brightline rule as to the reasonableness of prosecution[.]” *Cordance Corp. v. Amazon.com*, 631 F. Supp. 2d 484, 491 (D. Del. 2009). “The court must look to the prosecution history of the patent family as whole” such as whether the applicant was prosecuting other applications in the patent family. *Id.*

Courts have granted summary judgment of no prosecution laches in similar situations. *See e.g., Cordance*, 631 F. Supp. 2d at 490 (8 years from filing of priority application to issuance of final patent is not unreasonable); *Stambler v. RSA Security, Inc.*, 243 F. Supp. 2d 74, 76 (D. Del. 2003) (7 years from filing of priority application to issuance not unreasonable).³

³ Even in pre-GATT cases where a lengthy prosecution can extend patent term, courts have granted summary judgment of no prosecution laches despite a lengthy prosecution time. *Koninklijke Philips Elecs. N.V. v. Cinram Int’l, Inc.*, 2012 WL 4074419 (S.D.N.Y. Aug. 23, 2012) (18-year gap between initial filing and issuance in a pre-GATT case); *Studiengesellschaft Kohle mbH v. N. Petrochem. Co.*, 784 F.2d 351, 352 (Fed. Cir. 1986) (per curiam) (affirming the district court’s finding of no laches in a pre-GATT case despite prosecution period of over 20 years).

Here, Natera diligently prosecuted its patents to issuance to protect various aspects of the range of inventions described in its priority application – prosecuting no less than 13 applications during the relevant time period, 6 of which issued as patents. *See Stambler*, 243 F. Supp. 2d at 76 (finding no unreasonable delay where plaintiff “acted reasonably in prosecuting the various continuations and division applications during this time” and “ultimately received seven different patents in seven years” in a pre-GATT case); *Cordance*, 631 F. Supp. 2d at 491 (Cordance filed five applications during the 7 year period). Indeed, it is undisputed that the PTO examiner who examined each of Natera’s applications never suggested that Natera was engaging in dilatory conduct and never refused to issue any of the Asserted Patents based on such conduct, even though the examiner had the authority to do so.

Because Defendants cannot show any delay by Natera in prosecuting the cfDNA Patents, let alone any delay that was unreasonable and inexcusable under the totality of circumstances, their prosecution laches defense fails at step one.

2. No Evidence of Prejudice or Intervening Rights

Defendants have likewise failed to adduce any evidence of prejudice and intervening rights. Defendants admitted that they would not have changed their behavior even if they had known about Natera’s inventions. Further, Defendants were on notice of Natera’s inventions, and knew about Natera’s patenting activity in the general area. And Natera was within its legal rights to draft claims covering a competitor’s products. There is no prejudice to Defendants that can be attributed to Natera’s prosecution of the cfDNA Patents.

The lack of any prejudice is confirmed by Defendants’ 30(b)(6) witness Joshua Stahl, who was the Chief Operating Officer and Chief Scientific Officer of Defendant ArcherDX and is currently the President of Oncology at Defendant Invitae, and testified that ArcherDX has “known about Natera since at least 2016” and would not “have changed anything” in terms of its R&D,

product development, or commercialization had it known that Natera would be asserting its patents against Defendants. Ex. 25, Stahl 9/3/2021 Tr., 286:25-288:10. That is Defendants would have behaved no differently even if they had known the precise scope of Natera's patent claims. There can be no prejudice.

Defendants were also on notice of Natera's inventions and what Natera may claim at least as of on October 25, 2012, when the priority application, U.S. Appl. No. 13/300,235 ("the '235 application") was published.

Q: So this is the publication of the '235 application that Natera is claiming priority to; correct?

A: Yes. It appears to be that publication.

Q: Okay. And this was published on October 25, 2012, right?

A: Yes.

Q: And when a patent publication – or when a patent is published in this manner, would you agree that the subject matter is in the public domain?

A: I would agree that the subject matter that is disclosed in this publication is in the public domain as of its publication date.

Ex. 10, Kelley Tr., 60:21-61:10.

Further, Defendants were aware of Natera's patenting activity in this general area. It is undisputed that Defendants knew about application No. 13/335,043 ("the '043 application"), one of the 13 applications that Natera was prosecuting during the relevant period, when they identified it as a prior art reference during the prosecution of their patent. Ex. 14, NAT-AR-00708365 at NAT-AR-00708516-NAT-AR-00708527. Defendants knew about this application at least as of December 16, 2014. Ex. 15, NAT-AR-00708685 at NAT-AR-00708812-NAT-AR-00708819. Having chosen to continue developing their infringing products despite the risk, Defendants should not be permitted to misuse an equitable defense to excuse its own failure to respect Natera's intellectual property.

Likewise, “there is nothing improper” about filing claims intended to cover a competitor’s existing product. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) (“It should be made clear ... that there is nothing improper, illegal, or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor’s product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor’s product the applicant’s attorney has learned about during the prosecution of a patent application.”); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 n.2 (Fed. Cir. 2004) (not improper for an applicant to amend or insert claims during prosecution in order to encompass a competitor’s products, as long as the disclosure supports the claims). Although Defendants reference certain evidence regarding Natera’s personnel purportedly having been aware of ArcherDX’s commercialization activities (Ex. 24, Kelley Opening Report, ¶ 127), “similar considerations regarding the exercise of plaintiff’s patent rights and the effect on a competitor and the market” have been found “insufficient to establish prosecution laches.” *Cordance*, 631 F. Supp. 2d at 492. It is insufficient to raise an issue of fact to support allegations of prejudice.

In the context of prosecution laches, the Federal Circuit holds that the acceptable practice of amending claims to capture a new product in the marketplace “is easily distinguishable from appellants failure to further the prosecution of his application toward the issuance of any claims.” *In re Bogese*, 303 F.3d 1362, 1369 (Fed. Cir. 2002). It is the latter behavior that can support a finding of prosecution laches, not the former. *Id.*

On this undisputed record, Defendants cannot carry their burden to prove prosecution laches. Partial summary judgment of no unenforceability due to prosecution laches should be granted.

B. DEFENDANTS DO NOT HAVE A COGNIZABLE CLAIM FOR UNCLEAN HANDS

Defendants plead unclean hands as a separate defense but rely on the same deficient set of facts they use as support for prosecution laches, except for a cursory allegation that before the cfDNA Patent applications were filed, Natera's executive Debra Giorda, began working for ArcherDX, gained access to confidential information relating to ArcherDX's products in development, and then returned to Natera. Ex. 26, July 20, 2021 Defendants' Second Supplemental Objections and Responses to Interrogatory No. 11 at 29. Defendants however, have failed to show (or even allege) that Ms. Giorda disclosed any ArcherDX confidential information to Natera. Nor could they, as Defendants admitted that they were unaware of Natera having any of Defendants' confidential information. Defendants' unclean hands defense fails as a matter of law.

Unclean hands is an affirmative defense that closes the courthouse doors to a party that has "conducted [itself] as to shock the moral sensibilities of the judge." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 398 F. Supp. 2d 305, 310 (D. Del. 2005) (quoting *Gaudiosi v. Mellon*, 269 F.2d 873, 882 (3d Cir. 1959)). It relates only to those situations in which a party's conduct – such as falsification of evidence – is "offensive to the dictates of natural justice." *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001). Defendants must prove unclean hands with convincing evidence of "egregious" misconduct. *Sanofi-Aventis v. Advancis Pharmaceutical Corp.*, 453 F. Supp. 2d 834, 856 (D. Del. 2006); *Citizens Fin. Group, Inc. v. Citizens Nat'l Bank*, 383 F.3d 110, 129 (3d Cir. 2004).

To the extent Defendants' unclean hands defense is premised on the same deficient facts underlying their prosecution laches defense (D.I. 393, ¶¶ 274-327), it fails for the same reason why the prosecution laches defense fails. There is nothing improper – let alone egregious – about Natera claiming priority to a patent application filed 7-8 years ago and that has been continuously

prosecuted through various applications since filing, or drafting claims that cover a competitor's product. *See supra*, Section IV.A.

Defendants also perfunctorily allege that "Natera filed the applications leading to the Asserted Patents shortly after one of its senior executive, Ms. Debra Giorda, left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX's products in development, and then returned to Natera." D.I. 393, ¶ 329; *see also* Ex. 26, July 20, 2021 Defendants' Second Supplemental Objections and Responses to Interrogatory No. 11 at 29.

Notably absent from Defendants' allegation is any assertion that Natera gained access to Defendants' confidential information through Ms. Giorda or otherwise. Defendants could not have made the assertion because Defendants admitted to lacking any such evidence.

Indeed, Defendants' 30(b)(6) witness who testified on factual information regarding Defendants' unclean hands defense admitted that Defendants were unaware that Natera had taken any confidential information of Defendants.

Q All right. And you're not aware of any information that came to the defendants' attention that, in fact, Natera had taken any confidential information, correct?

THE WITNESS: Yes. We don't know what may or may not have been transferred, and I don't believe that -- that anything was found.

Ex 16, 11/22/2021 Stahl Tr., 19:20-20:3 (attorney objections omitted). In the absence of any evidence of transfer of Defendants' confidential information to Natera, Defendants' unclean hands defense collapses to the hollow prosecution laches defense that fails as a matter of law. A summary judgment of no unclean hands is appropriate.

C. DEFENDANTS HAVE FAILED TO DEMONSTRATE INEQUITABLE CONDUCT

Defendants' inequitable conduct defense rests on two legally insufficient premises unsupported by logic or evidence: (1) Natera's correction of inventorship of the cfDNA Patents is supposedly erroneous and done with a deceptive intent for the purposes of supporting an earlier

priority date; and (2) Natera's Executive Chairman and named inventor of the '220 Patent, Dr. Matthew Rabinowitz, failed to disclose during the prosecution of the '220 Patent certain documents from this and other litigations that addressed patentable subject matter, obviousness, and Section 112, and purportedly with a specific intent to deceive the PTO. But neither correcting inventorship nor failure to disclose litigation documents to the PTO is sufficient to establish inequitable conduct claim. Defendants must show by clear and convincing evidence but-for materiality and intent to deceive the PTO. *Ohio Willow Wood Co. v. Alsp S., LLC*, 735 F.3d 1333, 1345 (Fed. Cir. 2013) (But-for materiality requires a showing that the patentee "withheld or misrepresented information that, in the absence of the withholding or misrepresentation, would have prevented a patent claim from issuing."); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (intent requires a showing that the "the patentee acted with the specific intent to deceive the PTO.") "Intent and materiality are separate requirements. . . . a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality." *Therasense*, 649 F.3d at 1290.

Defendants cannot meet this high burden of proof for either of the two alleged conducts.

1. No Inequitable Conduct Based on Correction of Inventorship

Defendants cannot establish inequitable conduct based on Natera's correction of inventorship. Defendants have failed to adduce any evidence that the correction of inventorship – even if it were erroneous – is material to the issuance of any of the patents at issue. Similarly, there is simply no evidence that the correction of inventorship was made with any intent to deceive the PTO. Inventorship has no bearing on the proper priority date of the patents at issue, which is determined by the disclosure in the priority application, not by who the named inventors are.

a. There Is No Evidence of But-For Materiality

Defendants have no evidence that Natera's correction of inventorship is the but-for cause of the cfDNA Patents' issuance. Defendants argue that Natera's determination of inventorship was erroneous. As discussed below, Defendants cannot establish by clear and convincing evidence that Natera made an error in correcting the inventorship. *See infra*, Section IV.D. But even if there were an error, "[a]n error in determining inventorship is not by itself inequitable conduct." *Pro-Mold & Tool Co. v. Great Lakes Plastics*, 75 F.3d 1568, 1576 (Fed. Cir. 1996).⁴ Here, not only there is no evidence that correcting inventorship would have changed the issuance decision, even upon a finding of incorrect inventorship, a patentee may invoke section 256 to correct inventorship. 35 U.S.C. § 256.

Defendants appear to argue that Natera improperly corrected inventorship to support its priority claim. This argument turns the priority analysis on its head. While a properly determined priority date may guide the evaluation of who should be named as an inventor of the relevant patent claims, the priority date of a patent claim is not based on who is named as an inventor or who is not, but the disclosure of the priority application. Indeed, neither parties' experts relied on who the named inventors are in conducting their priority analyses. Defendants' inability to establish but-for materiality is fatal to their inequitable conduct claim.

b. No Evidence of Intent to Deceive the Patent Office

To meet the clear and convincing evidence standard, deceitful intent must be the only inference that can be reached from the evidence and Defendants have not adduced evidence that raises a genuine issue of fact as to intent. Rather, Natera and the named/removed inventors truly

⁴ Even intentional misrepresentations may not rise to the level of inequitable conduct if the "misrepresentation was not the but-for cause of the patent's issuance." *See Therasense*, 649 F.3d at 1291 (citing and discussing *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928)).

believed that there was an error in inventorship when they made the correction. *See supra*, Section III.C. And even if the correction in inventorship were made in error, no intent to deceive the PTO can be inferred. Inventorship determination is complicated and courts have found that inventorship error generally stems from misunderstanding the requirements of the legal term “inventor.” Defendants cannot meet their burden to prove intent to deceive the PTO.

Defendants bear a heavy burden to show deceptive intent—it must be the only conclusion from the evidence:

Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. However, to meet the clear and convincing evidence standard, the specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence.” Indeed, the evidence “must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.” Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. *See Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”).

Therasense, 649 F.3d at 1290-91 (internal citations omitted) (emphasis in original).

Here, not only there is no evidence of intent to deceive, but the evidence indicates that Natera and the inventors correctly made the changes to inventorship of the cfDNA Patents. *All of the inventors and Natera signed the declarations and testified that they believed the declarations were true at the time they filed it. See supra*, Section III.C. The inventors’ and Natera’s un rebutted belief that the declarations were true and correct when submitted to the PTO negates any reasonable inference of an intent to deceive the PTO. *See Cornell Univ. v. Illumina, Inc.*, Case No. 10-433-LPS-MPT, Opinion at 23 (D. Del. Jan. 10, 2017) (citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1332 (Fed. Cir. 2009) (affirming finding of no deceptive intent where inventor “believed the statement to be true at the time that he made it”)).

Defendants' insinuation that Natera and the inventors submitted false declarations to the patent office is not supported by any evidence. To the contrary, the immateriality of inventorship in issuance decision makes Defendants' insinuation implausible. "After all, a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes the falsehood will affect issuance of the patent." *Therasense*, 649 F.3d at 1292.

Moreover, even if Natera and the inventors had made an error in inventorship evaluation, a reasonable inference is that they made an error with no intent to deceive. Determining whether a scientist should be named an inventor is fraught with complications. *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020) ("Inventorship is sometimes easy to determine. *But sometimes it is complicated, as with complex projects involving many contributors at various times.*") (emphasis added). In this case, there is no doubt that the claimed inventions involved complex projects and many contributors over time. *See* Ex. 21, Natera's Seventh Supplemental Response to Interrogatory No. 1 at 330-428.

Courts grant summary judgment of no inequitable conduct under similar circumstances. In *Dealertrack Inc. v. Huber*, several purported joint inventors changed their position on whether they were inventors. No. 06-cv-2335, 2008 WL 11337833 (C.D. Cal. July 21, 2008). The court found that "the most likely inference from the evidence is that the Patentees misunderstood the exact requirements of the legal term of art 'inventor.' And, whatever the inference, the evidence that Patentees intended to deceive the examiner is certainly not clear and convincing." *Id.* at *4. Similarly, in *Dexcowin Global Inc. v. Aribex Inc.*, the patentee did not include his son as an inventor in the original application, but the son was later added during a re-examination proceeding. No. 16-cv-143, 2017 WL 3477748 (C.D. Cal. June 7, 2017). Here again, the Court noted the difficulties with inventorship determination and found no intent to deceive. *Id.* at *11 (citations

omitted). It is worth noting that even where a change of inventorship was found to be “a considered act that is unlikely to qualify as an omission through error” and the Court declined to credit the inventors’ testimonies of conception, the Court nonetheless did not find inequitable conduct. *Egenera Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020) (quoting district court decision).

Without any evidence of materiality or intent, Defendants cannot as a matter of law prove inequitable conduct by clear and convincing evidence.

2. No Inequitable Conduct Based on Alleged Failure to Disclose Litigation Documents to the PTO

Defendants allege that Dr. Matthew Rabinowitz engaged in inequitable conduct by failing to disclose to the Patent Officer pleadings and briefs from this and *Illumina* and *CareDX* litigations that addressed patentable subject matter, obviousness, and Section 112 with a specific intent to deceive the USPTO. D.I. 393, ¶ 338. Not only are the undisclosed documents immaterial to the issuance of patent claims, there can be no deceptive intent based merely on alleged failure to disclose certain documents. Defendants cannot meet the high burden of proof necessary to establish inequitable conduct

a. The Undisclosed Litigation Documents Are Not But-For Material

The undisclosed documents are not material to the issuance of the ’220 Patent claims. They include ArcherDX Inc.’s Answer, Answer to FAC, Answer to Second Amended Complaint, 12(c) Motion, and 12(c) Reply, as well as Natera’s CareDx Briefing and Natera’s Illumina Briefing. D.I. 393, ¶ 338, 343-349.

These litigation documents are not material for the examiner to assess whether the ’220 Patent claims were obviousness because the references the litigation documents characterize were already before the examiner. D.I. 393, ¶ 341, Thirteenth Counterclaim, ¶ 133; Ex. 4, ’220 Patent

at 3 and 15. It is well established that “an applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.” *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000). This is because where the examiner has the allegedly material reference, he or she is “free to credit or discount [the applicant’s] characterizations of [the prior art] in view of their own readings.” *Collectis S.A. v. Precision Biosciences*, 883 F. Supp. 2d 526, 535 (D. Del. 2012) (citing MPEP § 716.01(c)).

The Rule 12(c) briefs, Answer and *Illumina/CareDX* documents are not material for the examiner to assess whether the ’220 Patent claims are directed to patentable subject matter because the Court has ruled that the claims of the related ’814 Patent are directed to patentable subject matter based on the Rule 12(c) briefs. D.I. 59 at 17-20. Further, the court reviewed three of the seven pleadings from the *Illumina/CareDX* litigations as part of its ruling on the Rule 12(c) motion. D.I. 24 at 4, 15-18. As such, the ’220 Patent claims directed to a similar patentable subject matter would have issued even if the pleadings and briefing from the litigation had been before the examiner. *See August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278 (Fed. Cir. 2011) (dismissing inequitable conduct counterclaims based on withheld prior art where the jury found the prior art to not render the claims invalid).

The ArcherDx pleadings are also not material for the examiner to assess whether the ’220 Patent claims are supported under Section 112. There is no dispute that the patent application was in front of the examiner during prosecution and the examiner was fully free to credit or discount the written description and enablement support of the patent disclosure to the claims. D.I. 393, ¶ 342. Where the examiner has the entire patent disclosure, the examiner can credit or discount any characterizations of the patent disclosure in the ArcherDX pleadings. *See e.g., Collectis S.A. v. Precision Biosciences*, 883 F. Supp. 2d at 535. Defendants do not identify any specific material

information relevant for Section 112 purposes that was not disclosed to the PTO during the prosecution of the '220 Patent. *See, e.g., Analog Devices, Inc. v. Xilinx, Inc.*, No. 1:19-CV-2225, 2021 WL 466859, at *2-3 (D. Del. Feb. 9, 2021) (granting motion to strike the defendant's inequitable conduct defense where the defendant failed to demonstrate why the withheld information was material and non-cumulative).

b. Intent to Deceive the PTO Cannot Be Inferred Based on Alleged Failure to Disclose Litigation Documents

Defendants have not adduced any evidence, let alone clear and convincing evidence, to show that deceitful intent is the only inference that can be reached from non-disclosure of the litigation documents. Defendants have failed to adduce any evidence that Dr. Rabinowitz (i) knew of the specific passages in the thousands of pages of litigations documents, (ii) understood these specific passages and their purported but-for materiality and (iii) deliberately withheld the documents from the Patent Office. “One cannot assume that an individual, who [may] generally kn[o]w that a [litigation] existed, also knew of the specific material information contained in [a] reference [in the litigation].” *Exergen*, 575 F.3d at 1330. Even when a withheld reference is material, which is not the case here, simply alleging knowledge of a material reference and the non-disclosure of that reference does not establish specific intent. *Bayer Cropscience AG v. Dow Agrosciences LLC*, No. 1:10-CV-1045, 2012 WL 1253047, at *4- 5 (D. Del. Apr. 12, 2012) (specific intent could not be inferred from allegations that (1) named inventor knew of fact material to prosecution based on an article he co-authored; (2) inventor had duty to disclose fact to PTO; and (3) inventor failed to disclose information); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 (Fed. Cir. 2009) (intent requires that “a specific individual . . . withheld or misrepresented this information with a specific intent to deceive the PTO.”). As *Exergen* notes, an intent to deceive the PTO may not be inferred solely from some level of knowledge of a prior

art reference. *Id.* at 1331 (noting that “[t]he mere fact that an applicant disclosed a reference during prosecution of one application, but did not disclose it during prosecution of a related application, is insufficient to meet the threshold level of deceptive intent required to support an allegation of inequitable conduct”).

Defendants cannot prevail on defense of inequitable conduct. Summary judgment is appropriate.

D. DEFENDANTS HAVE FAILED TO ESTABLISH INVALIDITY BASED ON IMPROPER INVENTORSHIP

Defendants argue that the cfDNA Patents are invalid because they do not list the correct set of inventors. Ex. 27, Cooper Opening Report, ¶ 934. Defendants’ argument is without merit. *First*, even if there were an error in inventorship, and even if that error were deceptive, the recourse is correction, not patent invalidation. *Egenera*, 972 F.3d at 1376-77. *Second*, Defendants cannot meet the heavy burden to show improper inventorship as a matter of law because they have failed to identify any corroborating contemporaneous evidence supporting their inventorship claim, while leaving undisputed Natera’s extensive corroborating evidence of correct inventorship and evidence that the removed inventors could not have contributed to the cfDNA Patents. Summary judgment of no invalidity based on improper inventorship should be granted.

1. Correction, Not Invalidation, Is the Remedy for Inventorship Error

Defendants’ improper inventorship claim is nothing but a red herring. Even if Natera had identified an incorrect set of inventors, the remedy is correction, not invalidation. “A patent cannot be invalidated if inventorship can be corrected instead.” *Egenera*, 972 F.3d at 1376 (citation omitted). This is enshrined statutorily in 35 U.S.C. § 256(b):

The *error* of omitting inventors or naming persons who are not inventors *shall not invalidate the patent* in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction

of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

35 U.S.C. § 256(b) (emphasis added). The “error” in § 256 amended by the AIA “does not exclude ‘considered acts,’ or even ‘deceptive intention,’ from the meaning of ‘error.’ ‘Error’ is simply the incorrect listing of inventors.” *Egenera*, 972 F.3d at 1377; 35 U.S.C. § 256.⁵ “It is the inequitable-conduct rules that provide a safety valve in the event of deceit.” *Egenera*, 972 F.3d at 1377. Thus, even if the error in inventorship were made with deceptive intention, correction is the appropriate remedy, not invalidation. Defendants’ invalidity defense must fail as a matter of law. Summary judgment of no invalidity due to improper inventorship should be granted.

2. Defendants Cannot Meet the High Bar to Prove Improper Inventorship

Based solely on select testimony and resumes taken out of context and untethered to the conception of the inventions, Defendants contend that Natera did not identify the correct set of inventors when it corrected the inventorship of the issued cfDNA Patents pursuant to the administrative procedure under 37 C.F.R. § 1.324 in June 2021. Such evidence cannot overcome the presumption that “[t]he inventors as named in an issued patent are presumed to be correct.” *Hess v. Advanced Cardiovascular Sys. Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997) (quoting *AmaxFly Ash Corp. v. United States*, 514 F.2d 1041, 1047 (1975)). “The burden of showing misjoinder or nonjoinder of inventors is a heavy one and it must be proved by clear and convincing evidence.” *Id.* (quotation omitted).

⁵ Section 256 is a ‘savings provision’ with no limitations period – inventorship can be corrected at any time and, “[i]f a patentee demonstrates that inventorship can be corrected as provided for in section 256, a district court must order correction of the patent, thus saving it from being rendered invalid.” *Magnetar Techs. Corp. v. Six Flags Theme Parks Inc.*, 2017 WL 3279120 at *3 (D. Del. 2017).

The clear and convincing evidence necessary to prove nonjoinder requires corroborating contemporaneous evidence of the nonjoined inventor's contribution to the conception; an inventor's own testimony alone is insufficient. *Beriont v. GTE Labs. Inc.*, 601 Fed. Appx. 937, 940 (Fed. Cir. 2015); *Univ. of Colorado Foundation, Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1308 (Fed. Cir. 2003); *Trovan, Ltd. v. Sokymat SA*, 299 F.3d 1292, 1302 (Fed. Cir. 2002). Defendants have not sustained this heavy burden. To succeed on a misjoinder claim, Defendants "must also show that the persons to be removed did not contribute to the invention of any of the allowed claims." *Beriont*, 601 Fed. Appx. at 939 (citing *Hess*, 106 F.3d at 980). That evidence also cannot be just inventor testimony but must be corroborated with contemporaneous evidence. *Id.* at 940 (failing to prove misjoinder because the only evidence Beriont offered to show that he was the sole inventor is his own testimony, which was found "insufficient as a matter of law").

As to their nonjoinder claim, Defendants contend that Messrs. Babiarz, Constantin, Eubank, Sakarya, Kirkezar, and Constantin should not have been removed and Dr. Philippe Lacroute should have been added. For their misjoinder claim, Defendants contend that Drs. Gemelos, Ryan, Banjevic and Zemko were incorrectly added.

Defendants do not present any contemporaneous corroborating evidence, relying instead solely on cherry-picked excerpts of Natera scientists' testimony and their resumes untethered to the conception of the claimed inventions to falsely paint Defendants' version of reality. Ex. 27, Cooper Opening Report, ¶¶ 934-977. This is insufficient as a matter of law. Defendants' expert Dr. Cooper readily admitted that he only evaluated select testimony excerpts (and resumes in some instances) of the inventors in evaluating their contribution to the patents.

Q. Did you review any Natera document to evaluate the contribution of any of the added or removed inventors?

A. Right, so it was similar for the various names here. So it was primarily the deposition transcript. I think again there was quotes

from résumés from one or two of them but that was the primary basis. That was the basis, yes.

Q. So your analysis of the technical contribution of the inventors is based only on deposition excerpts you've cited in your expert report, correct?

A. Again looking at what they have said and looking at the patents themselves and at least one of their résumés, but yes, that was the basis. (Ex. 22, Cooper Tr. (Vol. 2), 252:12-25)

Specifically, for the nonjoinder claims, Dr. Cooper admitted that he only evaluated the patents and select testimony excerpts of the omitted inventors, Messrs. Babiarz, Constantin, Eubank, Sakarya and Kirkezar, and the resume of Mr. Constantin. (Ex. 22, Cooper Tr. (Vol. 2), 245:24-246:8; 247:23-248:2; 248:19-23; 249:16-20). Similarly, Dr. Cooper admitted that he only evaluated the patents and select testimony excerpts of the purported misjoined inventors, Drs. Gemelos, Demko, and Ryan. *See* Ex. 22, Cooper Tr. (Vol. 2), 250:2-251:10; 252:2-6.

Indeed, Dr. Cooper admitted that he did not believe it was necessary to evaluate Natera documents such as lab notebooks and similar documents in contravention of the above legal requirements. Ex. 22, Cooper Tr. (Vol. 2), 251:11-15; 252:7-11. "The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony." *Finnigan Corp. v. United States Int'l Trade Comm'n*, 180 F.3d 1354, 1366 (Fed. Cir. 1999). This rationale requiring corroborating evidence extends to inventorship challenges. *See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998). Defendants' sole reliance on inventor testimony fails to meet the clear and convincing standard of proof as a matter of law.

Tellingly, Defendants not only fail to present corroborating evidence to support their claim, they also do not address a single Natera document corroborating the invention of the correctly named inventors. Natera provided an approximately 100-page long detailed description of the contribution of the inventors, citing nearly 300 corroborating documents underlying inventorship

and the dates of the invention. Ex. 21, Natera’s Seventh Supplemental Response to Interrogatory No. 1 at 330-428. Defendants have no response to this evidence. Defendants’ expert Dr. Cooper did not address any of the corroborating documents. So even if Defendants had testimony from individuals who believed they were, in fact, inventors – which they indisputably do not – their defense would fail as a matter of law in the absence of corroborating evidence.

Moreover, undisputed evidence indicates that the removed inventors could not have contributed to the cfDNA Patents. The removed inventors joined Natera *after* the filing of the priority ‘235 application in November 2011. Joshua Babiarz joined Natera in December 2012 (Ex. 28, Babiarz Tr., 8:11-19), Tudor Constantin in January of 2013 (Ex. 29, Constantin Tr., 10:16-11:2 & Exh. 1), Lane Eubank became a Natera employee in January 2014 (Ex. 230, Eubank Tr., 13:3-17), Huseyin Kirkizlar joined Natera in May or June 2012 (Ex. 31, Kirkizlar Tr., 18:17-19:7), and Onur Sakarya in early 2014 (Ex. 32, Sakarya Tr., 14:20-21). An employee who joined Natera after the conception of the invention and the filing of a patent application disclosing the invention could not have contributed to the conception of that invention. Thus, as a matter of logic, these scientists could not have contributed to the inventions disclosed in the priority application – and claimed in the cfDNA Patents – and as a matter of law, could not have been inventors.

In sum, Defendants have not adduced any evidence, let alone clear and convincing evidence, of improper inventorship

E. THE ASSERTED PATENTS CLAIM WHAT THE APPLICANTS REGARDED AS THEIR INVENTIONS

Defendants contend that the asserted claims are invalid because the claims fail to state, “what the applicant regarded as the invention.” Ex. 27, Cooper Opening Report, ¶ 848. According to Defendants, the applicants regarded “techniques for target loci selection and primer design to avoid primer dimers” as its inventions, but the claims do not include any express elements that are

directed to loci selection (and hence primer selection) to avoid primer dimers. *Id.* at ¶¶ 853-854. Defendants attempt to obfuscate the facts; there is simply no evidence that the applicants regarded target loci selection and primer design as the only inventions disclosed in the Asserted Patents. That the asserted claims selectively focus on some of the inventions disclosed in the patents is legally irrelevant to the issue of validity. A patentee is not required to claim every invention disclosed in a single patent. *Cordis Corp. v. Boston Scientific Corp.*, 188 F. App'x 984, 990 (Fed. Cir. 2006) (“We have held that when a patent includes two inventive components, particular claims may be directed to one of those inventive components and not to the other.”). There is simply no legal ground for Defendant’s claim of invalidity.

To the extent Defendants argue that “techniques for target loci selection and primer design to avoid primer dimers” are the *only* invention described in the asserted patents, the argument is contradicted by the patent disclosure, which constitutes a clear and binding statement of what Applicants truly regarded as their inventions. As explained in the patent specification, the generation of non-target amplification products from primer dimers was a long-standing problem in simultaneously amplifying multiple DNA in a single reaction (“multiplex PCR”). Ex. 4, '220 Patent, 3:3-11. The specification then teaches the *claimed* multiplex nested PCR methods as one way to combat the off-target amplification caused by primer dimers. Ex. 4, '220 Patent, 86:29-47; 98:9-36; FIG. 6.

There is no dispute as to any of these facts. Indeed, Defendants’ expert Dr. Cooper admitted that the claimed nested PCR methods, including their use with cell-free DNA, are disclosed in the patent specification, including Figure 6. Ex. 22, Cooper Tr. (Vol. 2), 254:2-16; 255:4-258:24.

There is simply no evidence that the patentee did not regard the claimed methods as its inventions. Indeed, Dr. Cooper admitted that nowhere does the patent state that the claimed methods are not inventions.

Q. Can you point to anywhere in the patent specifications where the patentee says the claimed workflow is not an invention?

A. I don't recall anywhere where the specification of the patent says we have -- this is not an invention.

Ex. 22, Cooper Tr. (Vol. 2), 404:8-13.

Rather, the patent expressly discloses the claimed methods as inventions. *See e.g.*, Ex. 4, '220 Patent, Abstract ("The ***invention*** provides methods for simultaneously amplifying multiple nucleic acid regions of interest in one reaction volume . . ."); *Id.*, 2:54-56, Field of the Invention ("The ***present invention*** generally relates to methods and compositions for simultaneously amplifying multiple nucleic acid regions of interest in one reaction volume.") (emphasis added).

Defendants' reliance on *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336 (Fed. Cir. 2002), is misplaced.⁶ In *Allen Eng'g*, the court found the claims invalid as indefinite because they were ***contradicted*** by the specification. Courts following *Allen Eng'g* have required a finding of indefiniteness "'when there is ***an irreconcilable contradiction***' within the patent, i.e., between the patent specification and patent claim, or, relatedly, a 'logical inconsistency or contradiction' between the specification and the claims[.]" *Guard Ant Health, Inc. v. Foundation Medicine, Inc.*, No. 17-1616-LPS-CJB, 2019 WL 5092632, at *4 (D. Del. Oct. 11, 2019) (internal citations omitted). "When there is no such contradiction between the specification and relevant claims, the claims are not indefinite under *Allen Eng'g*." *Id.*

⁶ *Allen Engineering* is the only legal authority Defendants identify to support this theory of invalidity. Defendants' Final contentions, at 75; Cooper Opening Report, ¶ 848; Cooper Tr. (Vol. 2), 384:2-385:15; 389:18-390:7; 389:18-390:7 ("My understanding of the legal basis here is exactly what is written at that first sentence of paragraph 848, that, if the claim is invalid, if the claim fails to state what the applicant regarded as the invention. That is my understanding.").

Here, unlike in *Allen Engineering*, there is no contradiction between the specification and the asserted claims and Defendants have not even attempted to identify one. As discussed above and as admitted by Dr. Cooper, the claims match the express disclosure in the specification. Ex. 22, Cooper Tr. (Vol. 2), 254:2-16; 255:4-258:24. Because the patent specification expressly describes the claimed methods and describe them as “inventions,” and Defendants have failed to come forward with any evidence to show that the inventors considered the claimed methods *not* to be their inventions, the asserted claims are not invalid for failing to state what the applicant regarded as the invention.

Defendants’ argument appears to be a surrogate to recapture Defendants’ proposed definition for “target loci” that this Court previously rejected. Defendants had argued that the claim term “target loci” should be limited to nucleic acid sequences “subject to amplification using primers with sequences complementary to the nucleic acid selected to avoid primer dimer side products.” D.I. 243 (Markman Opinion), at 5. The Court rejected this construction explaining, “Restricting the ambit of ‘target loci’ to only those that ‘avoid primer side products’ would improperly import an additional limitation from the specification in the absence of any indication of a clear intent by the patentee to do so.” *Id.* at 6. This is precisely what Defendants are attempting to do so now. By arguing that “*techniques* for target loci selection and primers *to avoid primer dimers*,” is what the patentees purportedly considered their invention and should have been claimed, Defendants are resuscitating their rejected argument that the asserted claims should be limited to those methods that avoid primer dimers. Defendants’ attempt to backdoor in their rejected claim construction position should be rejected.

For all these reasons, summary judgment is appropriate that the asserted claims are not invalid for alleged failure to set forth “what the applicant regarded as the invention” is appropriate.

F. THE ASSERTED CLAIMS OF THE '708, '814 AND '220 PATENT ARE NOT INDEFINITE

Defendants repeat the same indefiniteness arguments they made and lost during the claim construction process: (1) the asserted '708 Patent claims, which require the annealing temperature for the PCR reaction to be “greater than a melting temperature of the at least 2 primers,” are indefinite because different methods for measuring the melting temperature of a primer supposedly yield significantly different values; and (2) the claim term “sequencing tag” recited in the asserted claims of the '814 and '220 Patents is indefinite because a POSA purportedly would not understand its bounds with reasonable certainty. Defendants, however, have failed to present any additional relevant evidence not already considered and deemed to be insufficient by the Court (*see* D.I. 243, at 10, 12), compelling a finding of no indefiniteness of these asserted patent claims.⁷

1. The Term “a Melting Temperature of the at least 2 Primers” Does Not Render the Asserted '708 Patent Claims Indefinite

Defendants repeat the arguments they made during claim construction. According to Defendants, the asserted claims of the '708 Patent are indefinite because the methods disclosed in the patent will allegedly yield different melting temperature values for a given primer, one of the methods disclosed in the patent is not usable for calculating melting temperature of longer primers, and a POSA would not know whether the claims are limited to the use of the two methods disclosed in the patent. Defendants failed to present clear and convincing evidence to support their argument at the *Markman* stage. They failed to do so again now. The undisputed evidence is that as of 2014, the priority date of the inventions claimed in the '708 Patent, the two methods disclosed in the

⁷ A patent claim is indefinite if, “viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). Indefiniteness is a question of law for the court. *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1317 (Fed. Cir. 2015). The facts giving rise to a finding of indefiniteness must be proved by clear and convincing evidence. *Koninklijke*, 2012 WL 4074419, at *6. T.

patent – the empirical ultraviolet method and the Primer3/Santa Lucia software method – would result in melting temperature values within only 1°C of difference. The patent discloses a method for calculating melting temperatures of longer primers and a POSA would know to use the disclosed methods.

A claim limitation requiring a measurement is indefinite only if “(1) different known methods exist for calculating a claimed parameter, (2) nothing in the record suggests using one method in particular, and (3) application of the different methods result in materially different outcomes for the claim’s scope such that a product or method may infringe the claim under one method but not infringe when employing another method.” *Ball Metal Bev. Container Corp. v. Crown Packaging Tech., Inc.*, 838 F. App’x 538, 542 (Fed. Cir. 2020); *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 630 (Fed. Cir. 2015) (“the patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select”). “[T]he mere possibility of different results from different measurement techniques does not render a claim indefinite.” *Ball Metal Bev.*, 838 F. App’x at 542.

Here, the patent record provides using an empirical method for measuring actual melting temperature (the ultraviolet method) and a software method to estimate melting temperature (Primer3/Santa Lucia software) in the absence of an actual measurement. Indeed, as the Court noted, “the patent contains guideposts for the POSA” and “expressly discloses two measurement tools: ultraviolet light or Primer3/ Santa Lucia software.” D.I. 243, at 12.

At *Markman*, Defendants failed to show any evidence that the empirical ultraviolet light method and the Primer3/Santa Lucia software available as of 2014 priority date of the ’708 Patent would yield significantly different results. As Natera explained during the claim construction

proceeding, improvements made by Owczarzy and colleagues to the Primer3/Santa Lucia software—published in the publication Owczarzy 2008 (Ex. 33) —allowed the difference between software calculated melting temperatures and those measured by the empirical method to be within less than 1°C. (*Id.* at 5351 (“Using the algorithm of Figure 9 with the correction formulas presented herein, the T_m can be predicted within the average accuracy of 1°C. Earlier models are less accurate and in some cases lead to large errors of more than 10°C.”)) The Primer3/Santa Lucia software as of 2014 incorporated improvements taught in Owczarzy 2008 publication such that the results it generated were not significantly different than those from the ultraviolet light method.⁸ The newer data in Owczarzy 2008 was before the Court during the *Markman* proceeding and the Court found that the asserted patent claims were not indefinite based on the record before the Court. Rather than evaluating Owczarzy 2008 or present any new evidence, Defendants continue to rely on the same outdated data from Owczarzy 2004 publication they previously presented during the *Markman* proceedings. Ex. 27, Cooper Report, ¶ 896.

The Primer3/Santa Lucia software as of 2014 incorporated improvements such that the ultraviolet light method and 2014 Primer/Santa Lucia software did not yield significantly different results. These improvements are taught in Owczarzy 2008 publication. Ex 33. Defendants, however, did not evaluate Owczarzy 2008, presenting instead the same outdated data from Owczarzy 2004 publication they had previously presented during the *Markman* proceedings.

⁸ The patent does not require that the primer melting temperature be less than 1°C than the annealing temperature. Thus, if two methods result in melting temperature within 1°C, the difference in the two results is not a material difference. As the Supreme Court stated, “[t]he definiteness requirement, so understood, mandates clarity, while recognizing absolute precision is unattainable. . . . ‘the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.’” *Nautilus*, 572 U.S. at 910 (citation omitted).

Dr. Cooper admitted that he did not evaluate Owczarzy 2008 in rendering his opinion, but instead relied only on the outdated Owczarzy 2004 data:

Q. Now, going back to the Koressaar paper, since it included data collected from the 2004 Owczarzy paper, correct?

A. Yes.

Q. And so, then, the data or the information that is analyzed is information available as of 2004, correct?

A. Well, they were -- that paper described melting temperature data collected from experimental assessments, but certainly, it was generated and published in 2004.

Ex. 22, Cooper Tr. (Vol. 2), 446:3-13.

Q. Have you seen this document [Ex. 1249, Owczarzy 2008] before?

A. I'm not sure. I can't remember if I looked at this or not.

Q. Did you consider this document in rendering your opinion?

A. Certainly, if I cited it, I did. honestly, I'd have to look at my appendix to be sure.

Q. Please go ahead and look at the appendix.

A. I'm not seeing it in the Appendix B.

Q. So you do not cite to this paper anywhere in your expert report, do you?

A. Again, I can't say one way or the other. ***If it's not in the appendix, I guess, I would have to assume I did not.*** But I'm drawing a blank on it right now. So I can't say one way or the other right now, to be honest. ***Certainly, it's not in Appendix B, so it's not described as being cited.***

Ex. 22, Cooper Tr. (Vol. 2), 448:11-449:12 (emphasis added).

Given that the Court already found the outdated data in Owczarzy 2004 to be insufficient to establish indefiniteness of the asserted claims, Defendants' continued reliance on Owczarzy 2004 cannot sustain their indefiniteness claim. Notably, Defendants fail to identify any primer from any of the products practicing the claims that yielded different melting temperature values, further underscoring the lack of proof.

Beyond the evidence the court already found insufficient at *Markman*, the only additional evidence, Defendants identify are excerpts of testimony by inventors Zachary Demko and Matthew Hill, a Chester paper disclosing two techniques different from the ultraviolet light and

Primer3/Santa Lucia software and von Ahsen paper for the proposition that melting temperatures depend on reaction conditions (*id.* at ¶¶ 902-903, 913). But none of this evidence suggests indefiniteness, let alone allowing Defendants to carry their burden of clear and convincing proof.

- Dr. Zemko merely testified that the claim language did not place a limit on how to determine melting temperature, not that the specification did not provide appropriate guideposts as the court had found. Ex. 27, Cooper Opening Report, ¶ 893.
- Dr. Hill testified that he did not “remember the precise details,” he had not “done that work” and his “vague recollection” is that the difference between the Santa Lucia method and actual empirical calculation is “within a couple of degree Celsius.” *Id.* at ¶ 896. Notably, Dr. Hill did not testify that this was his understanding as of 2014, the priority date of the ’708 Patent and in any event, his testimony was based on vague recollection and without performing any work.

As for the Chester paper, it teaches two measurement tools, Marmur and Doty formula or Rychlik method, neither of which is identified in the patent, a fact Defendants readily admit. Ex. 27, Cooper Opening Report, ¶¶ 902-905. Defendants do not provide any evidence why a POSA would use these techniques as opposed to the ultraviolet measurement taught in the patent. Further, Defendants provide no evidence that the Marmur and Doty formula or Rychlik method would result in materially different results compared to the ultraviolet method taught in the patent. The Von Ahsen paper merely reiterates the importance of what is claimed—melting temperature should be calculated based on reaction conditions.

Defendants also repeat their previously failed argument that the Primer3/Santa Lucia method cannot be used to measure melting temperature of primers with more than 35 nucleotides. Ex. 27, Cooper Opening Report, ¶¶ 897-899. Even if this were true, a POSA would know to use

the ultraviolet light method taught in the patent to measure the melting temperature of primers with more than 35 nucleotides. Defendants' continued failure to present clear and convincing evidence compels the same finding previously reached by the Court at the *Markman* stage—the “melting temperature” term in the asserted claims of the '708 Patent is not indefinite.

2. The Term “Sequencing Tag” Does Not Render the Asserted '814 and '220 Patents Indefinite

Defendants contend that the asserted claims of the '814 Patent and '220 Patent are indefinite because the claim term “sequencing tag” is a coined phrase that is not defined in the patents' specification and the patents fail to inform a POSITA as to the term's meaning. Ex. 27, Cooper Opening Report, ¶ 890. This Court has previously rejected Defendants' argument and provided a definition for “sequencing tag.” D.I. 243, at 9 (“Sequencing tag” means “A nucleic acid sequence introduced to carry out the process of high throughput sequencing”).

Defendants' citation to select excerpts of inventors' testimony does not undermine the Court's definition. Ex. 27, Cooper Opening Report, ¶¶ 924-925. The inventors testified that they needed to evaluate the patent specification to understand the meaning of sequencing tag in the context of the claims. None of the inventors were asked if they understood the Court's definition of sequencing tag and whether they would know the bounds of the court's definition of “sequencing tag.” Some of the inventor testimony relied upon by Defendants is included below:

Q. Let's go back to Claim 1 of the '220 Patent. We had talked about that last step that's referring to a sequencing tag. Do you know what a sequencing tag is?

A. **In the context of the document, I would – I don't know. I would have to read through the document, refresh my memory of this document to understand the context of this document.**

Ex. 34, Gemelos Tr., at 118:4-13 (emphasis added).

Q. As a – someone who believes they're an inventor on the '220 patent and a patent agent and an employee at Natera for 11 years, you don't think you can lend clarity as to the meaning of sequencing tag in the '220 patent?

A. I think in both that case and this case, the – it – in order to give clarity, understand what the meaning is, there needs to be a thorough diligence done. I need to understand what the patent says. I need to understand the various arguments around it. And no, I don't think it's objective or obvious, no matter what my qualifications may be.

Q. It's not objective or obvious what a sequencing tag is?

A. As I pointed out earlier, people who write patents have the liberty to be their own lexicographer, and they can use it to mean whatever they want. **You've already shown me text that indicates sequencing tag refers to multiple different things. And so it's going to depend entirely on how it's defined and how it's used.** And I can't give that clarity without more due diligence and – and understanding what the patent says.

Ex. 11, Demko Tr. at 150:10-151:14 (emphasis added).

Other than select inventor testimony, Defendants adduce no additional evidence that was not before the Court during the Markman proceeding. Defendants provide no evidence that a POSA would not understand what a sequencing tag is with reasonable certainty as defined by the Court. This Court found that Defendants had failed at the Markman stage to provide clear and convincing evidence of indefiniteness. D.I. 243, at 10. Given that Defendants have adduced no additional evidence that could possibly meet their heavy burden, Defendants have failed to prove as a matter of law that the asserted claims of the '814 and '220 Patents are indefinite.

G. NATERA'S MOTION TO PRECLUDE CERTAIN EXPERT TESTIMONY SHOULD BE GRANTED

Natera respectfully moves to exclude the testimony of Defendants' experts Nathan K. Kelley on prosecution laches and Gregory Cooper on the inventorship defense. Expert testimony is admissible only if:

- (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data;
- (c) The testimony is the product of reliable principles and methods;
- and
- (d) The expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589-96 (1993). Defendants bear the burden of establishing, by a preponderance of the evidence, that their experts' qualifications and opinions comply with the Federal Rule of Evidence 702. *See Daubert*, 509 U.S. at 592-93 (citation omitted). Defendants cannot meet their burden here.

1. Mr. Kelley's Legal Opinion on Prosecution Laches Should Be Excluded in Its Entirety

Mr. Kelley's legal opinion on prosecution laches should be stricken in its entirety because: (a) it has nothing to do with PTO practices and procedures, the purported area of Mr. Kelly's "specialized knowledge," and thus unhelpful to the trier of fact; and (b) is the product of unreliable principles and methods. Fed. R. Evi. 702; *AstraZeneca UK Ltd., IPR v. Watson Labs., Inc. (NV)*, C.A. No. 10-915-LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) ("[T]he judges in this District have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances.") (citing cases)).

a. Mr. Kelley's Opinions Have Nothing to Do with PTO Practices and Procedures and Unhelpful to the Trier of Fact

According to Mr. Kelley, his role in this case is "as an expert on USPTO practice and procedure[.]" Ex. 24, Kelley Opening Report, ¶ 88. Rather than bringing his specialized knowledge to bear, Mr. Kelley's opinions on prosecution laches are untethered to PTO practice and procedure. Instead, Mr. Kelley simply states his version of the relevant facts and offers his conclusions of alleged delay and intervening rights. *See generally* Ex. 24, Kelley Opening Report.

"[T]his Court has routinely excluded the testimony of patent law experts" reaching beyond the narrow topic of PTO practices and procedures "largely because such testimony frequently amounts to the proffering of impermissible legal conclusions." *W.L. Gore & Associates, Inc. v. C.R. Bard, Inc.*, No. 11-545-LPS-CJB, 2015 WL 12815314, at *3 (D. Del. 2015); *Lannet Company Inc. v. KV Pharm., Drugtech Corp.*, No. 08-338-JJF, 2009 WL 10657988, at *4 (D. Del. 2009)

(“The District of Delaware has for some time excluded testimony by patent law experts on substantive issues of patent law including inequitable conduct.”). This is precisely the case here.

That Mr. Kelley is *not* opining on matters of PTO practice and procedure is plain from his report. Nowhere in his report does Mr. Kelley discuss PTO practice or procedure, such as how patent applications are examined in the U.S. Patent Office and how it is relevant to the case at bar. Nor does Mr. Kelley’s report include any discussion of or even a citation to the Manual of Practice Examining Procedure (“MPEP”), which, as Mr. Kelley acknowledges, includes procedures that patent examiners are required or authorized to follow, including guidance to examiners on whether to issue a laches rejection. Ex. 10, Kelley Tr., 53:23-54:1, 56:1-10, 56:17-57:10.

Instead, Mr. Kelley offers no more than legal conclusions untethered to his specialized knowledge. Rather than opining on PTO practice and procedures, Mr. Kelley simply interprets the facts of the case and assesses how they fit within the legal framework of prosecution laches, Mr. Kelley is doing nothing more than what a trier of fact does and adds no additional value. This Court has routinely excluded the testimony of patent law experts that goes beyond PTO practices and procedures and should do so here as well. *Revlon Consumer Prods. Corp. v. L’Oréal S.A.*, Civil Action No. 96–192 MMS, 1997 WL 158281, at *3 (D. Del. Mar. 26, 1997) (concluding that while the proffered patent law expert could testify with respect to “matters of PTO practice and procedure[,]” it would not allow him “to testify as an expert on inequitable conduct; to do otherwise would usurp the respective functions of the ... Court”); ; *see also W.L. Gore & Associates*, 2015 WL 12815314, at *3; *Lannet*, 2009 WL 10657988, at *4.

b. Mr. Kelley’s Speculation on Natera’s Motives Is the Product of Unreliable Principles and Methods and Unhelpful to the Trier of Fact

An expert’s testimony must be based upon “the methods and procedures of science rather than subjective belief or supported speculation and that the experts have good grounds for his or

her brief.” *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). Mr. Kelley, however, speculates on why Natera presented the asserted patent claims in 2019 rather in 2011. Ex. 24, Kelley Opening Report, ¶¶ 111-125. Mr. Kelley also interprets deposition testimony of Natera’s witnesses and other documents and surmises about Natera’s purported state of mind. Ex. 24, Kelley Report, ¶ 116 (“If it were truly the case that Natera’s 2019 prosecution efforts were merely necessitated by a maturing oncology market, it is difficult to believe that so few of the claims Natera sought would actually be directed to oncology . . .”); ¶ 117 (“Natera was in fact interested in seeking patent protection, but it did not become sufficiently interested until ArcherDX’s business had grown more.”)). This is not Mr. Kelley’s role

Moreover, Mr. Kelley’s opinion about Natera’s motives is nothing more than rank speculation, the antithesis of the requirement that an expert testimony is “the product of reliable principles and methods.” Fed. R. Evi. 702. Mr. Kelley makes a big deal about Natera purchasing samples of ArcherDX’s FusionPlex products, which are used with RNA samples, in 2016. Ex. 24, Kelley Opening Report, ¶¶ 48-49, 51-59, 121. But he does not explain why or how the purchase of products for use with *RNA* samples, *not cfDNA* (cell-free DNA) samples, had anything to do with Natera’s motive or decision to prosecute the asserted claims of the cfDNA Patents, which each requires *cell-free DNA* sample, *not RNA* sample. To impute that purchase of kits for *RNA* samples somehow implicated a deliberate delay by Natera in presenting *cfDNA* claims for prosecution is baseless conjecture and should be precluded. *In re Rosuvastatin Calcium Patent Litig.*, MDL NO. 08-1949, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (“Generally, expert witnesses are not permitted to testify regarding ‘intent, motive, or state of mind, or evidence by which such state of mind may be inferred.’”) (internal quotations omitted).

In sum, Mr. Kelley's opinion "constitute[s] an improper attempt to offer opinions from a legal expert about what the facts of the record indicate to him about" the elements of prosecution laches. *W.L. Gore & Associates, Inc. v. C.R. Bard, Inc.*, 2015 WL 12815314 at *5 (D. Del. 2015). Mr. Kelley's opinion on prosecution laches should be stricken in its entirety and Mr. Kelley should be precluded from testifying on this subject.

2. Dr. Cooper Should Be Precluded from Testifying on Inventorship

Defendants' expert Gregory Cooper opines that the cfDNA patents are invalid for improper inventorship. Ex. 27, Cooper Opening Report, ¶¶ 934-977; Ex. 12, Cooper Reply Report, ¶¶ 199-216. Dr. Cooper's opinion on inventorship should be stricken because (a) Dr. Cooper does not undertake a proper inventorship analysis and (b) proffers as expert opinion his interpretation of witness testimony, testimony a trier of fact is equally capable of understanding.

a. Dr. Cooper's Inventorship Analysis is Legally Insufficient and Unreliable

Dr. Cooper failed to perform the correct inventorship analysis. Dr. Cooper did not perform the requisite claim-by-claim analysis of inventorship. Inventorship must be shown on a claim by claim basis. *Egenera, Inc. v. Cisco Systems, Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020); *see also Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 706-709 (D. Del. 2012) (engaging in a claim-by-claim analysis regarding alleged improper inventorship). A claim-by-claim analysis is necessary because who should be named as an inventor may vary depending on what, exactly, is claimed and what, exactly, a court determines the claim scope to be. *Id.* Dr. Cooper also did not tether the inventor testimonies to the asserted claims of each of the cfDNA Patents. "A person must contribute to the conception of the *claimed* invention to qualify as a joint inventor." *Intermec Techs. Corp. v. Palm Inc.*, 738 F. Supp. 2d 522, 562 (D. Del. 2010), *aff'd*, 466 F. App'x 881 (Fed. Cir. 2012) (emphasis in original) (quoting *Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1303

(Fed. Cir. 2010) (affirming Judge Robinson’s determination that university did not prove joint inventorship by clear and convincing evidence)).

Dr. Cooper did not evaluate the contribution of the inventors to each claim. He did not consider any corroborating evidence. Instead, Dr. Cooper relies solely on cherry-picked excerpts of Natera witness testimony unbound to the asserted claims or time, and the patents (and a resume in one case) in his inventorship analysis. *See supra* Section IV.D. “It is well-established, however, that when a party seeks to prove conception through an inventor’s testimony the party must proffer evidence, in addition to the inventor’s own statements and documents, corroborating the inventor’s testimony.” *Apator Mitros APS v. Kampstrup A/S*, 887 F.3d 1293, 1295 (Fed. Cir. 2018) (quotations omitted). “Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1171-72 (Fed. Cir. 2006).

Dr. Cooper readily admits that he did not review any document other than the select testimony excerpts of Natera scientists in his inventorship evaluation. *See supra* Section IV.D. Dr. Cooper testified that he did not believe it was necessary to evaluate Natera documents such as lab notebooks and similar documents. Ex. 22, Cooper Tr (Vol. 2), 251:11-15; 252:7-11. Given that Dr. Cooper failed to evaluate any document other than select deposition transcripts (and a resume in one case), he failed to identify any corroborating evidence and his opinion is unreliable. *See EMC Corp. v Pure Storage, Inc.*, 154 F. Supp. 3d 81, 106 (D. Del. 2016) (“Because EMC did not present independent corroborative evidence of Dr. Li’s testimony regarding the date of conception, Dr. Li’s testimony regarding inventive facts must be disregarded.”).

b. Dr. Cooper's Opinion Is Nothing More Than His Interpretation of Witness Testimonies – The Province of a Trier of Fact

By proffering nothing more than his interpretation of cherry-picked testimonies of Natera's scientists, Dr. Cooper's opinion is unhelpful to the trier of fact, in contravention of Federal Rule of Evidence 702. A trier of fact is equally capable of reviewing and understanding a scientist's testimony. An expert is not necessary to provide a self-serving spin on witness testimony. Dr. Cooper's entire inventorship opinion should be stricken, and Dr. Cooper should be precluded from testifying on this subject.

V. CONCLUSION

For the reasons set forth above, Natera respectfully requests the Court to grant its Motion for Partial Summary Judgment and to Preclude Certain Expert Testimony.

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CERTIFICATE OF SERVICE

I hereby certify that on January 21, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 21, 2022, upon the following in the manner indicated:

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